

Effectiveness of Foot Orthoses to Treat Plantar Fasciitis

A Randomized Trial

Karl B. Landorf, PhD; Anne-Maree Keenan, MAppSc; Robert D. Herbert, PhD

Background: Plantar fasciitis is one of the most common foot complaints. It is often treated with foot orthoses; however, studies of the effects of orthoses are generally of poor quality, and to our knowledge, no trials have investigated long-term effectiveness. The aim of this trial was to evaluate the short- and long-term effectiveness of foot orthoses in the treatment of plantar fasciitis.

Methods: A pragmatic, participant-blinded, randomized trial was conducted from April 1999 to July 2001. The duration of follow-up for each participant was 12 months. One hundred and thirty-five participants with plantar fasciitis from the local community were recruited to a university-based clinic and were randomly allocated to receive a sham orthosis (soft, thin foam), a prefabricated orthosis (firm foam), or a customized orthosis (semirigid plastic).

Results: After 3 months of treatment, estimates of effects on pain and function favored the prefabricated and customized orthoses over the sham orthoses, although only the effects on function were statistically significant. Com-

pared with sham orthoses, the mean pain score (scale, 0-100) was 8.7 points better for the prefabricated orthoses (95% confidence interval, -0.1 to 17.6; $P=.05$) and 7.4 points better for the customized orthoses (95% confidence interval, -1.4 to 16.2; $P=.10$). Compared with sham orthoses, the mean function score (scale, 0-100) was 8.4 points better for the prefabricated orthoses (95% confidence interval, 1.0-15.8; $P=.03$) and 7.5 points better for the customized orthoses (95% confidence interval, 0.3-14.7; $P=.04$). There were no significant effects on primary outcomes at the 12-month review.

Conclusions: Foot orthoses produce small short-term benefits in function and may also produce small reductions in pain for people with plantar fasciitis, but they do not have long-term beneficial effects compared with a sham device. The customized and prefabricated orthoses used in this trial have similar effectiveness in the treatment of plantar fasciitis.

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THE PLANTAR FASCIA, OR plantar aponeurosis, is a tough, fibrous, connective tissue structure that spans the plantar surface of the foot from the inferior heel to the toes.¹ Pain emanating from this structure is most often referred to as plantar fasciitis.²

Plantar fasciitis is one of the most common foot complaints. One recent American study³ estimated that there are approximately 1 million patient visits per year to office-based physicians and hospital departments for treatment of plantar fasciitis. The disorder is particularly prevalent in runners and people who are overweight⁴⁻⁹ and it is also prevalent in people with inflammatory arthritis.¹⁰⁻¹³ Plantar fasciitis makes up approximately 25% of all foot injuries in runners¹⁴ and up to 8% of all injuries to people participating in sporting activities.¹⁵⁻¹⁷

Foot orthoses are commonly used in the conservative treatment of plantar fasciitis. It is thought that foot orthoses reduce the symptoms of plantar fasciitis by reducing strain in the fascia during standing and ambulation.^{18,19} Cadaveric research shows that orthoses reduce foot pronation, collapse of the longitudinal arch, and associated elongation of the foot.^{20,21} There are many different types of orthotic devices, although one of the primary distinctions is between relatively inexpensive prefabricated orthoses and more expensive customized orthoses. A handful of randomized controlled trials²²⁻²⁵ have evaluated the effects of foot orthoses from a patient's perspective. However, systematic reviews of these trials have concluded that the evidence for the effectiveness of foot orthoses in the treatment of plantar fasciitis is poor and that further investigation with rigorous randomized clinical trials is needed.²⁶⁻²⁸

Author Affiliations:

Department of Podiatry, School of Human Biosciences, La Trobe University, Australia (Dr Landorf); Academic Unit of Musculoskeletal Disease, University of Leeds, Leeds, England (Ms Keenan); and School of Physiotherapy, University of Sydney, Sydney, Australia (Dr Herbert).

Published randomized trials of orthoses for plantar fasciitis suffer from a number of methodological weaknesses. To our knowledge, none compared the effects of orthoses with a no-treatment or sham group, and none assessed long-term outcomes (the longest follow-up was 3 months). Two of the 4 trials were underpowered, none assessed function (disability), 3 had losses to follow-up of at least 15%, and only 1 explicitly analyzed by intention to treat.²⁸ To address these weaknesses, we conducted a randomized trial that evaluated the short- and long-term effectiveness of foot orthoses in the treatment of plantar fasciitis.

METHODS

The study, a 3-armed, participant-blinded randomized trial, was conducted from April 1999 to July 2001. Participants were allocated to groups that received sham orthoses, prefabricated orthoses, or customized orthoses. Ethics approval for the project was obtained from the university's ethics review committee. All participants provided written informed consent prior to recruitment.

PARTICIPANTS AND RANDOMIZATION

The trial was conducted at a university podiatry clinic, which services a local community of approximately 200 000 people. Recruitment was assisted by advertisements in local newspapers. Consecutive patients who had a clinical diagnosis of plantar fasciitis and who had experienced symptoms for at least 4 weeks were invited to participate. They were excluded if they had a history of a major orthopedic or medical condition (eg, inflammatory arthritis or diabetes) that may have influenced the condition. One hundred and forty-seven patients with plantar fasciitis were screened, of whom 136 were eligible to participate. All 136 patients gave written informed consent to participate in the trial.

Participants were allocated to 1 of 3 groups according to a computer-generated random allocation sequence. The allocation sequence was concealed from potential participants and from the investigator who recruited participants. After recruiting a participant and completing baseline assessments, the investigator ascertained that participant's allocation by contacting the center holding the allocation sequence (either by telephone or e-mail). Patients were considered to have entered the trial at the moment their allocations were divulged to the investigator.

CLINICAL PROTOCOL

Each participant was assessed using a standardized assessment by the investigator, an experienced podiatrist (K.B.L.). Neutral position plaster casts²⁹ were taken by the investigator; these were later used to fabricate the foot orthoses or size the prefabricated orthoses. Participants were advised that they would receive soft, medium, or hard orthoses molded specifically to their feet and were given a further appointment 2 to 3 weeks later to issue the orthoses. No other treatments (eg, anti-inflammatory drugs or corticosteroid injections) were allowed during the 12 months that the participants were in the trial.

Following the initial appointment, participants were allocated to 1 of 3 groups (hereafter sham, prefabricated, and customized groups), and the orthoses were fabricated in the intervening 2 to 3 weeks. The sham foot orthosis was fabricated by molding 6-mm, soft (120 kg/m³) ethyl vinyl acetate foam over an unmodified cast of the foot. This device was designed

to provide minimal structural support for the foot. The prefabricated foot orthosis was a three-quarter-length (retail mold) Formthotic (Foot Science International, Christchurch, New Zealand) dispensed using the manufacturer's instructions. This device was made from a firm-density polyethylene foam that is sufficiently thick to fill the arch area and prevent the orthosis from flattening, thus providing support for the foot. The customized foot orthosis was fabricated at a commercial orthotic laboratory (The Orthotic Laboratory, Melbourne, Australia) using principles described by Hice.³⁰ A plaster cast was posted to the neutral calcaneal stance position, and a hard plastic shell was vacuum molded over the cast. The shell was made from semirigid polypropylene, and a firm foam heel post was applied inferior to the heel. This device is relatively rigid and is designed to provide significant support for the foot and influence the position of the foot relative to the leg.

The prefabricated and customized orthoses were selected based on a survey of podiatric physicians, representing those that are commonly prescribed.³¹ All devices were made to look as similar as possible (ie, in color and shape) given the materials used, and participants were blinded to which device they had received. The allocated orthoses were dispensed 2 to 3 weeks after the initial appointment, and then outcomes were measured at 3 and 12 months.

OUTCOME MEASURES

The primary outcomes, nominated a priori, were pain and function at 3 and 12 months. These were measured with the pain and function domains of the Foot Health Status Questionnaire,³² which has previously been validated (content, criterion, and construct validity) across a wide spectrum of pathological conditions, including skin, nail, and musculoskeletal disorders. It has a high test-retest reliability (intraclass correlation coefficients range, 0.74-0.92) and a high degree of internal consistency (Cronbach α range, 0.85-0.88).³² It was selected on the basis of a detailed comparison³³ of its performance with an alternative tool, the Foot Function Index.³⁴ Secondary outcomes are not reported here, but the data are available from the first author (K.B.L.). To minimize the assessor's influence on participant responses, all outcomes were measured at the beginning of each appointment prior to any interaction between the participant and the assessor.

STATISTICAL ANALYSIS

Primary outcome data were analyzed according to a preplanned protocol. Separate analyses were conducted on 3-month and 12-month outcomes. To maximize precision of estimates, analysis of covariance was conducted using a linear regression approach.^{35,36} We prespecified that the baseline measure (either pain or function at baseline) would be used as the only covariate in each analysis. For the analysis of pain we adjusted for pain at baseline. For the analysis of function we adjusted for function at baseline. Data were analyzed by intention to treat. The primary aim was to estimate the magnitude of effects, but we also conducted hypothesis tests. We used the Kruskal-Wallis test to determine if there were differences between groups in the number of days between review appointments. Hypothesis tests were considered significant if $P < .05$.

We determined the sample size of 136 before conducting the trial. This sample size provides a 90% probability of detecting an effect between any of the orthoses of 15 points on the pain domain of the Foot Health Status Questionnaire. The sample size calculation assumed an SD of 20 and a loss to follow-up of 15%. We conservatively ignored the extra precision provided by covariate analysis when estimating the sample size.

Table 1. Baseline Characteristics*

Variable	Type of Orthosis		
	Sham (n = 45)†	Prefabricated (n = 44)	Customized (n = 46)
Age, y	48.5 (9.6)	47.3 (11.6)	49.2 (12.0)
Women, No. (%)	30 (67)	25 (57)	34 (74)
Height, cm	168.3 (8.6)	168.6 (9.4)	165.9 (7.5)
Weight, kg	83.5 (14.0)	93.5 (18.0)	83.2 (16.6)
BMI	29.6 (4.9)	32.9 (6.1)	30.3 (6.1)
Subjects with both feet affected, No. (%)	23 (51)	21 (48)	19 (41)
Self-reported time on feet per day, h	9 (3)	9 (3)	9 (3)
Median period of symptoms in months (range)	12 (1-240)	11 (2-360)	12 (2-360)
FHSQ score; range of 0-100 points			
Foot pain	45.1 (20.6)	42.1 (20.0)	48.4 (20.9)
Foot function	68.2 (26.8)	56.1 (27.3)	62.2 (22.0)

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); FHSQ, Foot Health Status Questionnaire (0 corresponds to the worst foot health; 100, the best).

*Values are given as mean (SD) except where noted.

†One participant withdrew from the sham group owing to illness prior to receiving treatment and without knowing which intervention she had been allocated. No baseline data were available for this participant.

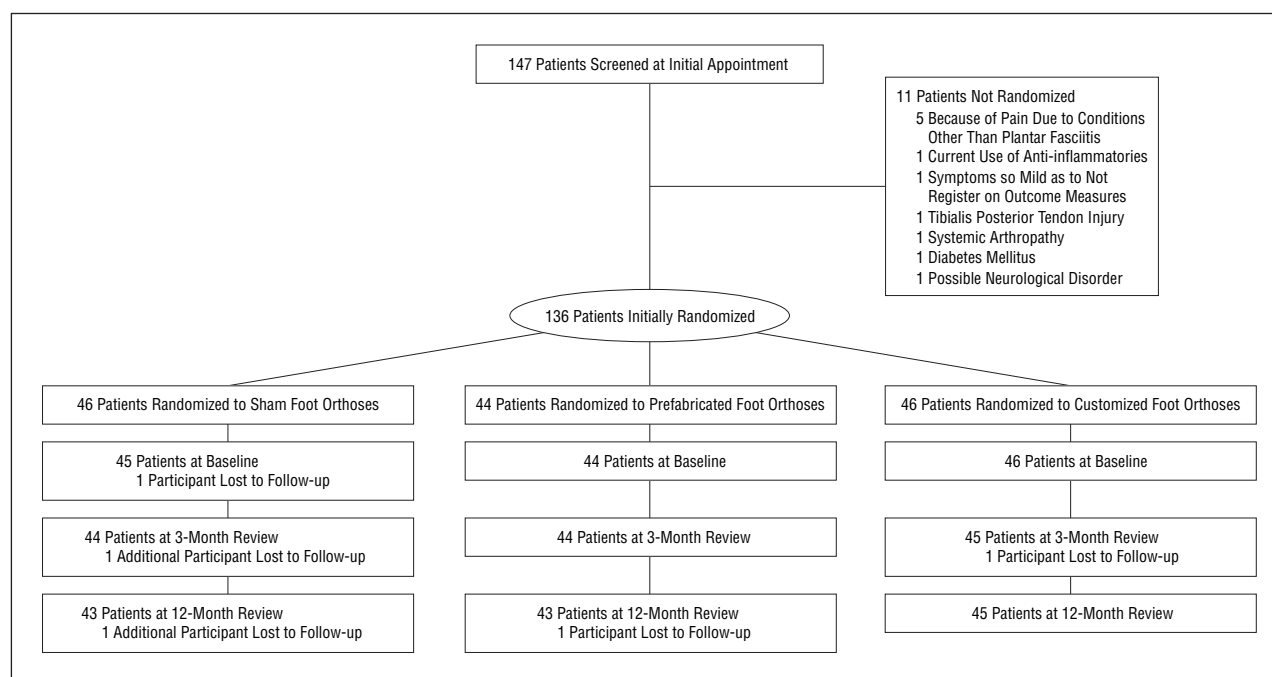


Figure 1. Participant flowchart.

RESULTS

Table 1 provides the baseline characteristics of participants. Participants in the 3 groups appeared to be generally well matched although the prefabricated group had a mean weight that was approximately 10 kg heavier than that of the other 2 groups. Correspondingly, the body mass index (calculated as weight in kilograms divided by the square of height in meters) of the prefabricated group was also greater by 2.6 to 3.0 kg/m². Participants reported experiencing symptoms for a median period of 12 months (range, 1-360 months); hence, the sample consisted primarily of patients with relatively chronic symptoms.

The progression of participants through the trial is presented in **Figure 1**. There were no differences in follow-up times between the groups at either the 3-month ($P = .37$) or 12-month ($P = .83$) reviews. For the 3-month review, the number of days (median [interquartile range]) for the groups were sham, 92 (88-103); prefabricated, 90 (84-100); and customized, 91 (85-98). For the 12-month review, the number of days (median [interquartile range]) was 375 (371-383) for the sham group; 373 (369-387) for the prefabricated group; and 373 (371-382) for the customized group.

One participant from the sham group withdrew owing to illness prior to receiving treatment and without knowing which intervention she had been allocated. Be-

Table 2. Mean (SD) Outcomes Scores At Baseline and 3-Month and 12-Month Follow-ups, and ANCOVA-Adjusted Estimates of Mean (95% Confidence Interval) Differences Between Groups*

Outcome	Outcome Score			ANCOVA-Adjusted Estimates of Effects†		
	Sham	Prefabri-cated	Customized	Prefabricated vs Sham	Customized vs Sham	Prefabricated vs Customized
Pain						
Baseline	45.1 (20.6)	42.1 (20.0)	48.4 (20.9)			
3-Month Review	63.4 (21.5)	71.4 (23.2)	71.8 (20.6)	8.7 (-0.1 to 17.6)	7.4 (-1.4 to 16.2)	1.3 (-7.6 to 10.2)
3 Months - Baseline	18.3 (22.5)	-29.3 (27.7)	-23.4 (26.9)			
12-Month Review	82.3 (18.0)	83.8 (18.0)	83.1 (21.4)	2.2 (-5.6 to 10.0)	-0.1 (-7.8 to 7.7)	2.3 (-5.6 to 10.1)
12 Months - Baseline	-37.2 (23.5)	-41.7 (24.2)	-34.7 (24.6)			
Function						
Baseline	68.2 (26.8)	56.1 (27.3)	62.2 (22.0)			
3-Month Review	79.7 (22.3)	81.8 (22.8)	84.1 (19.9)	8.4 (1.0 to 15.8)	7.5 (0.3 to 14.7)	0.9 (-6.3 to 8.1)
3 Months - Baseline	-11.5 (16.1)	-25.7 (24.3)	-21.9 (21.9)			
12-Month Review	87.8 (20.6)	89.5 (19.0)	90.2 (17.8)	5.5 (-2.0 to 13.0)	4.3 (-3.0 to 11.6)	1.2 (-6.1 to 8.5)
12 Months - Baseline	-19.6 (26.0)	-33.4 (25.4)	-30.0 (22.5)			

Abbreviation: ANCOVA, analysis of covariance.

*The bold entries are the primary outcomes, which were nominated a priori.

†Between-group mean differences were adjusted for the baseline score of the outcome.

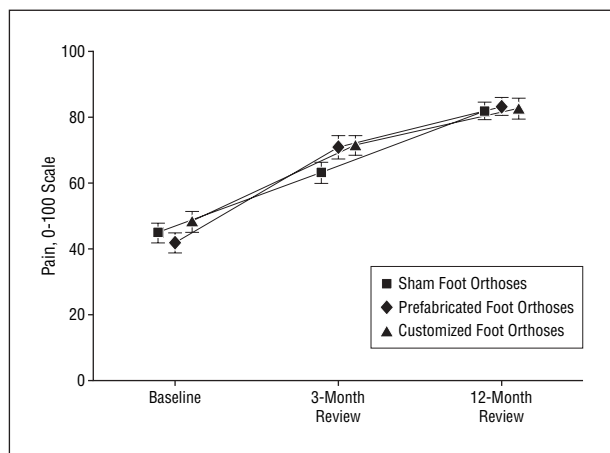


Figure 2. Foot Health Status Questionnaire pain scores (mean [SE]) at baseline, 3-month review, and 12-month review.

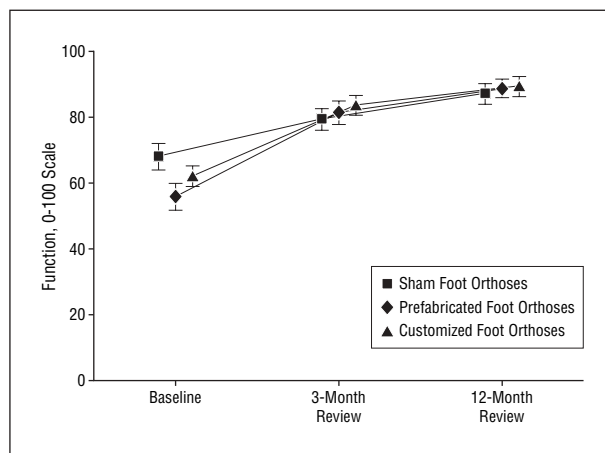


Figure 3. Foot Health Status Questionnaire function scores (mean [SE]) at baseline, 3-month review, and 12-month review.

cause the baseline data were measured when the orthoses were issued to participants, no data were available for this participant. Four other participants were each unavailable for 1 of the 2 follow-up measures. Consequently, loss to follow-up over the 12 months of the trial was 2.9%. At 3 months, 7% of participants (4 in the sham, 3 in the prefabricated, and 2 in the customized group) had broken protocol (eg, taken anti-inflammatory drugs, received a corticosteroid injection, or used alternative orthoses or a night stretch splint). Of these participants, 2 in the sham group began using alternative orthoses. At 12 months, the percentage of participants who broke protocol had increased to 23% (12 in the sham, 11 in the prefabricated, and 8 in the customized group). The number using alternative orthoses at this time point was 7 in the sham group, 2 in the prefabricated group, and 1 in the customized group.

All 3 groups experienced improvements in pain and function at 3 and 12 months compared with baseline, but differences between groups were small (**Table 2**,

Figure 2, and **Figure 3**). The prefabricated and customized groups demonstrated benefits in the short term (ie, at 3 months) compared with the sham, but not in the long term (ie, at 12 months). The intention-to-treat analysis at 3 months demonstrated that the prefabricated and customized groups had greater improvements in pain than the sham group: adjusted mean differences of 8.7 points (95% confidence interval [CI], -0.1 to 17.6) for the prefabricated group and 7.4 points (95% CI, -1.4 to 16.2) for the customized group. These differences were not statistically significant, although the prefabricated device approached significance ($P = .05$ and $.10$, respectively). The mean difference for pain between the prefabricated and customized groups was negligible (adjusted mean difference of 1.3; 95% CI, -7.6 to 10.2).

Both the prefabricated and customized groups also had better function than the sham group at 3 months: adjusted mean differences of 8.4 points (95% CI, 1.0-15.8) for the prefabricated group and 7.5 points (95% CI, 0.3-14.7) for the customized group. These differ-

ences were statistically significant ($P = .03$ and $.04$, respectively). The mean difference between the prefabricated and customized groups for function was negligible and not statistically significant (adjusted mean difference of 0.9; 95% CI, -6.3 to 8.1). Differences in pain and function at 12 months were also negligible (Table 2).

COMMENT

Prefabricated orthoses and customized orthoses produced small short-term benefits. Both the prefabricated and customized orthoses produced statistically significant improvements in function (mean effects at 3 months compared with sham orthoses of 8.4 points for prefabricated orthoses and 7.5 points for customized orthoses). Prefabricated and customized orthoses also seemed to reduce pain compared with sham orthoses (effects of 8.7 points and 7.4 points, respectively), although these differences were not statistically significant. Effects on both pain and function were small, and it is not clear if they are large enough to be clinically important.

To express these results in a more tangible way, we dichotomized function data by considering that an improvement in function occurred when function increased by more than one third of the baseline values. The prefabricated foot orthosis produced 1 additional improved outcome for every 6 people treated for 3 months, and the customized foot orthosis produced 1 additional beneficial outcome for every 4 people treated for 3 months.

Some clinicians and patients with plantar fasciitis will consider effects of this magnitude to be sufficient to justify the use of orthoses. In that case, it is necessary to decide whether to use prefabricated or customized orthoses. Data from this trial indicate that there is little difference between the effects of the prefabricated and customized orthoses. Provision of prefabricated orthoses is usually considerably less expensive than customized orthoses. (Typical costs of supply and fitting at the time of the study were of the order of \$45-\$90 for prefabricated orthoses and \$225-\$300 for customized orthoses.)

The results of this trial also need to be viewed in light of 2 limitations. First, the participants had chronic symptoms; effects of orthoses may be different for patients who have been experiencing plantar fasciitis for less time. However, other baseline characteristics of the participants are similar to a typical patient with plantar fasciitis. Second, the assessor was not blinded. This is a potential source of bias. Nevertheless, outcome measures were self-reported by participants who were blind to allocation, and outcome data were obtained at the beginning of each appointment prior to interaction with the assessor. We believe these procedures provide little opportunity for the assessor to bias measures of outcome.

Comparison of the baseline characteristics of the 3 groups revealed that the prefabricated group had a mean weight that was approximately 10 kg heavier than the other 2 groups. We did not adjust for this difference because we had prespecified that we would adjust only for differences in baseline outcome measures, and post hoc selection of covariates is known to introduce bias.³⁷

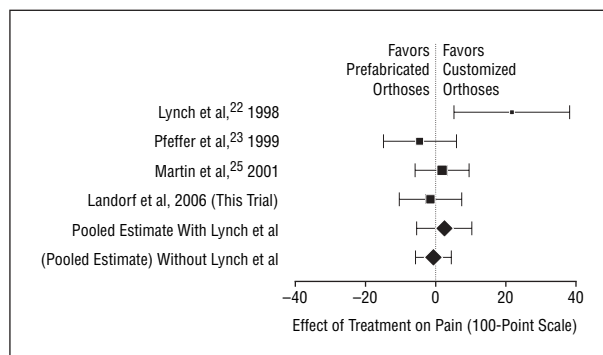


Figure 4. Estimates (means, shown as squares with area proportional to sample size, and 95% confidence intervals [bars]) of short-term effects on pain from 4 studies evaluating prefabricated and customized foot orthoses for plantar fasciitis. Pooled estimates (random effects model), including and excluding 1 study that included a cointervention, are shown as diamonds. All studies evaluated pain at 3 months except for the study by Pfeffer et al,²³ which evaluated at 2 months.

Previous randomized trials evaluating foot orthoses for plantar fasciitis²²⁻²⁵ suffer from a number of methodological weaknesses. Our trial improves on the published trials in a number of ways: to our knowledge, it is the first to compare real orthoses with a sham orthosis; it followed up participants for 12 months; it was adequately powered; it used validated health status measures and measured function as well as pain; it was analyzed by intention to treat; and it had losses to follow-up of just 3%.

Four trials have now compared the effectiveness of prefabricated and customized orthoses in treating plantar fascia pain. Data from these trials have been pooled and are shown in **Figure 4**. One trial²² provided participants in the customized orthosis group with the extra short-term treatment of taping their feet (ie, the other groups did not receive taping). Inclusion or exclusion of the trial makes little difference to the pooled estimate (Figure 4), which is similar to the estimates from our study. Both our study and the pooled estimates from the extant randomized trials indicate that there is no substantive difference between prefabricated and customized orthoses in their short-term effectiveness in treating pain in patients with plantar fasciitis.

In conclusion, this trial shows that commonly prescribed customized and prefabricated orthoses produce small short-term benefits for people with plantar fasciitis compared with a sham device. Long-term effects on pain and function are negligible. The effects of prefabricated and customized orthoses are similar.

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Correspondence: Karl B. Landorf, PhD, Department of Podiatry, School of Human Biosciences, La Trobe University, Victoria 3086, Australia (k.landorf@latrobe.edu.au).

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